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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,872	06/29/1998	SYDNEY M PUGH	3477/116	6664

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/029,872

Applicant(s)

PUGH ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,10,12,13,22,23,25-29,32-35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,10,12,13,22,23,25-29,32-35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Specification

The disclosure is objected to because of the following informalities:

Upon review of the specification, it was noticed that continuing data might have to be inserted on page 1 before the first line. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 12, 13, 22, 23, 25, 32, ~~33~~, 34, and 38 are rejected under 35

U.S.C. 102(b)* as being anticipated by Ruys (article entitled "Silicone-doped Hydroxyapatite"). Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxylapatite and silicone which is converted to alpha-TCP by sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). The result of Ruys' process is a powder or bulk material. Furthermore, since the material of Ruys is the same as that claimed, it would inherently have the same resorbability and *in vivo* response as claimed; see page 72.

*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996.

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With regard to claim 2, the higher concentration of silicone results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50 mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

With regard to claim 12, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same solubility properties such that this claim language is fully met.

With regard to claim 25, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same structural properties of Figure 14 as claimed. It is noted that Figure 14 is of very poor quality such that details thereof are not readily discernable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 26 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) alone.

With regard to claim 10, Ruys uses tetraethyl orthosilicate instead of tetrapropyl orthosilicate as claimed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use tetrapropyl orthosilicate in place of tetraethyl orthosilicate because Applicant has not disclosed that tetrapropyl orthosilicate provides an advantage,

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is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with tetraethyl orthophosphate because it is from the same class of compounds and is quite chemically similar thereto. Therefore, it would have been an obvious matter of design choice to modify Ruys to obtain the invention as specified in claim 10.

With regard to claim 26, Ruys fails to disclose the particle size as claimed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use the claimed particle size because Applicant has not disclosed that the claimed particle size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the claimed particle size because it is in the size range of a powder form and many chemical agents and drugs are provided in such a form. Therefore, it would have been an obvious matter of design choice to modify Ruys to obtain the invention as specified in claim 26.

With regard to claim 33, Ruys discloses the use of the material with^{an} implantable prosthesis, but not the prosthetic device specifically; see page 71, line 5. However, it would have been clearly prima facie obvious to use the material of Ruys on an implantable device for the reasons that Ruys discloses; i.e. for the enhancement of bone ingrowth into prosthetic materials.

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Claims 27-29, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Davies (WO 94/26872). Ruys meets the claim language except for the presence of bone cells or their excreted materials. However, Davies teaches that it was known to prepare implants by culturing bone cells on the material or implant in order to test it; see the whole document, especially the abstract.

With regard to claims 27-29, the Examiner posits that the claimed matrix would inherently be formed in the Davies modified Ruys device due to the same device being exposed to the same cells for a sufficient time for such matrix to form.

Response to Arguments

In response to the traversal of the Ruys Section 102 rejection that the recited claims are neither taught nor suggested thereby, the Examiner maintains that the present claims are either anticipated or obvious over Ruys. The Examiner does not see any feature of the claims that is lacking or unobvious over Ruys as applied. For this reason, the rejections have been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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